PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Aerosol Device

We, MERCK & Co., a corporation duly organized and existing under the laws of the State of New Jersey, United States of America, of Rahway, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to dispensing devices for pressurized vessels of the aerosol type and, more particularly, to metering valves for use with pressurized vessels containing atomizable or volatilizable material.

Vessels containing aerosols and the like are presently used for many purposes. In many instances it is desirable to have a standardized amount of the pressurized material released from the container. This invention provides apparatus for isolating and discharging a predetermined amount of the material in a pressurized container.

The use of dispensers of the aerosol type has also become increasingly popular in the administration of medicaments. One problem associated with the administration of medicaments in the form of a spray or aerosol is controlling the amount or dosage of medicine received by the patient. Attempts to solve this problem have resulted in the appearance of numerous varieties of dosage valves and metering devices throughout the art. The majority of such devices are unreliable in controlling quantity, while others are generally expensive in construction due to the requirements of critical seals and close tolerances.

A further problem associated with administering aerosol-type medicaments is ensuring that the medicament is properly received by the patient. The patient must receive all of the medicament that is discharged from the dispenser if the amount of the dosage is to have any significance. The medicament must also be delivered to the area that requires treatment. This is especially true of medicaments intended for treatment of respiratory ailments. Even though a mouthpiece or nosepiece surrounds the spray nozzle of the conventional medicating device, there is no guarantee that the patient will be inhaling when the spray is released. More important, there is no guarantee that the patient will be just beginning to inhale when the spray is released. In order for all of the medicament to be delivered deep into the respiratory system, the patient should be at the beginning of inhalation at exactly the moment the measured dosage is released.

According to the invention, there is provided an aerosol container and spray device for use in administering small measured amounts of the contents of the aerosol container to a human being through his mouth or nostril, said device including:

(a) a container for a pressurized fluid and a metering chamber for measuring small amounts of the pressurized fluid;

(b) manually actuated means for filling said metering chamber with said small amount of pressurized fluid from the remainder of the pressurized fluid in the container; and

(c) conduit means for directing the metered amount of pressurized fluid in the form of a spray into the mouth or nostril of the human being, when the said amount of pressurized fluid is released from the metering chamber, in which:

(i) the said manually actuated means may be released without enabling any fluid which may be contained in the metering chamber from escaping into the conduit means; and

(ii) the device includes means for releasing the contents of the metering chamber into the conduit means whereby the fluid can pass into the respiratory tract of the individual.

One advantage of the construction is that

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a measured amount of medicament is released when the patient first begins to inhale so that the medicament is drawn deeply into the respiratory tract and will consequently be of greater benefit to the patient. The patient need not consciously try to co-ordinate breathing and valve triggering since it is automatic. Another advantage of this invention is that the duration or intensity of the inhalation does not influence the dosage or the amount of medicament that is released since the dosage is standardized regardless of individual differences in operation or breathing. Still other advantages are inherent in the construction of the dosage chamber providing for: the elimination of gases or fluids from the dosage chamber before it is filled with medicament, positioning of the chamber outside the container during storage so that the medicament does not "settle out" during storage (most medicaments mix well in large amounts but not in small amounts), the chamber can be made small and accurate, there are no extraneous articles (such as springs, plunger stems, etc.) in the chamber for the medicament to collect upon, and the volume of the chamber is not influenced by miscellaneous parts within the chamber. These features add to the assurance that the amount of each dosage will be standard regardless of the frequency of use. Still other advantages will be apparent from the accompanying drawings, the description that follows, and the claims herein set forth.

IN THE DRAWINGS:

Fig. 1 is a perspective view of the external portions of the pneumatically released aerosol device;

Fig. 2 illustrates the use of the pneumatically released aerosol device by a patient;

Fig. 3 is an exploded view showing the various parts of the pneumatically released aerosol device according to this invention;

Figs. 4—10 are sectional views of the pneumatically released aerosol device showing different relative positions of various parts in order to illustrate the operation, the individual figures being described as follows:

Fig. 4 shows the aerosol device in the initial position, which is the position after the metered quantity of the contents of the aerosol container have been discharged;

Fig. 5 shows the position of the parts in the first step of the cocking operation, when the push button has been partially depressed;

Fig. 6 shows the position of the parts in the second step of the cocking operation when the push button has been further depressed;

Fig. 7 shows the position of the parts in the third step of the cocking operation, when the push button has been fully depressed;

Fig. 8 shows the position of the parts in the final step of the cocking operation, when the push button has been released and the device is in cocked position;

Fig. 9 shows the position of the parts in the first step of the pneumatic releasing operation;

Fig. 10 shows the position of the parts in the final step of the pneumatic releasing operation, and shows the contents of the metering chamber being discharged into the mouthpiece;

Fig. 11 is a sectional view of a second embodiment of the invention;

Fig. 12 is a perspective view of the retainer and valve stem used in the embodiment of Fig. 11;

Fig. 13 is a sectional view of a manually released aerosol device; and

Fig. 14 is an enlarged fragmentary sectional view of a portion of Fig. 13.

In the drawings, the same reference numerals are applied to identical parts in all embodiments and such identically numbered parts are substantially identical in structure, function, and operation. Therefore, to eliminate confusing duplication, these parts, their interrelationship and their function will be described only in conjunction with a single embodiment, such description applying to all embodiments where these parts appear.

Referring to Fig. 1, the dosage apparatus 11 is shown in the normal operating position with the push button 13 below the container portion 15. The apparatus 11 could, of course, operate in any position with most aerosol materials, but many medicaments will be of such a nature that the most advantageous positional attitude for optimum operation will be the position shown in the drawings. From the external view (Fig. 1), a push button 13, container 15, mouthpiece 17 and vent openings 19—19 can be seen.

Fig. 2 shows how the patient uses the apparatus by placing the mouthpiece 17 in his mouth. The apparatus 11 has been "cocked" since the patient has pressed the button 13. The preferred construction provides a mouthpiece 17 shaped so that the container position tilts away from the face. As soon as the patient starts to inhale, the dosage, which was metered out by the patient's pressing button 13, will be released into the patient's oral cavity. Continued inhalation will pass the dose of medicament deeper into the respiratory system.

Referring to Figs. 3 and 4, the valve portion 21 is mounted on the container 15. The container 15 has a flange 23 around an opening 25 and an extension 27 projecting below the flange 23 that aids in enclosing and retaining valve portion 21. The method and construction for attaching and mounting the valve portion 21 to the container 15 may be modified so that a variety of sizes and shapes of containers can be attached to the valve

portion 21. In the embodiment shown herein, the container 15 has been constructed to fit the valve conveniently allowing many of the parts to be press-fitted together thereby saving time and expense in assembling the apparatus.

A valve body or actuator retainer 29 is press-fitted into the container extension 27 over the opening 25 and fits against a seal such as a gasket 31. The retainer 29 is cylindrical with a flange 33 at one end. A central bore 35 passes through the flanged end of the retainer 29 and the length of the bore 35 is substantially equal to the height of the flange 33. The bore 35 communicates with a larger bore 37 that continues from bore 35 to the opposite end of the retainer 29. Two slots 39—39, in the cylindrical wall of the retainer 29 and substantially opposite one another, extend from the unflanged end of the retainer 29 to a point about midway between the ends of retainer 29. A groove 41, on the outside surface of the cylinder walls, extends from the end of each slot 39 to the flange 33. A hole 43 passes through the wall of the retainer 29 at each slot 39 and the centre of the hole 43 is aligned with the centerline of the slot 39. A detent ball 45 fits snugly into each hole 43. A passage 47, aligned with a line passing through both of the slots 39—39 and positioned in about the middle of flange 33, communicates between the exterior cylindrical surface of flange 33 and an orifice chamber 49 that is positioned in the interior cylindrical surface of flange 33. The orifice chamber 48 is open to the bore 35.

A metering plunger 50 includes a valve stem 51 that is fitted snugly into bore 35 and extends through bore 37. Two guides 53—53 extend in a winglike manner from the outer surface 55 of valve stem 51 and are positioned in the slots 39—39. Each guide 53 has an edge 37 substantially parallel to the outer surface 55 of the valve stem 51, an end 59 that is inclined or at an approximately forty-five degree angle with respect to the outer surface 55, and an opposite end 61 substantially perpendicular to the outer surface 55. The valve stem 51 has two centrally located bores. One is a piston bore 63 that communicates with one end of the valve stem 51 and the other is a smaller piston rod bore 65 that extends from piston bore 63 to the opposite end of valve stem 51. An expergatory piston 67 fits into the bore 63. A piston rod 69, attached to piston 67, fits into bore 65 and extends from one end of the valve stem 51. The metering plunger 50 also includes a valve stem plug 71 that is press fitted to valve stem 51 over the end opening of bore 63, and an expurgatory piston seal 73 is disposed between the end of stem 51 and plug 71 covering the end of piston 67. The cylindrical side wall 74 of plug 71 engages the inner edge of gasket 31 in a sliding sealing fit. The plug 71 has an enlarged end 75 that bears on seal 31 preventing the stem 51 from moving out of bore 35. A metering chamber 77 is centrally located in plug 71 and has an orifice 79 communicating with the outside surface of plug 71 that, in the position of the apparatus as shown in Fig. 4, communicates with the orifice chamber 49. Resilient means such as a spring 81 bears against a seal 83 at the end of bore 37 and the ends 61—61 of guides 53—53 urging the valve stem 51 downward so that the enlarged end 75 of valve stem plug 71 bears on seal 31. The spring 81 is not absolutely necessary to operation of the valve since most propellants that are used in aerosol-type containers generate enough pressure to supply the energy for urging the valve stem to its downward position (Fig. 4).

A cylindrical actuator 85 slips over the outside of the retainer 29. The outer edge of a flanged end portion 87 fits against the inside surface 89 of the container extension 27. Two ridges or guides 91 extend inwardly from opposite sides of the inside surface 93 of actuator 85 and are fitted into retainer slots 39—39 and retainer grooves 41—41. At the end of actuator 85 (the end opposite the flanged end 87) each guide 91 is wider forming an "ear" or projection 95. Each projection 95 has an edge 97 that is parallel to the inner surface 93 of actuator 85 and an edge 99 that is inclined or at an approximate forty-five degree angle with respect to inner surface 93.

A valve cocking button 13 is affixed to the end of the piston rod 69. The button 13 is cup-shaped, with the outside surface of the sidewall 101 slidably engaged with the inner surface 89 of container extension 27. An opening 103 is formed in the sidewall 101 providing communication from the exterior to the interior of button 13. A ridge 105 is positioned on the outside of sidewall 101 opposite the opening 103. The ridge 105 fits into a groove 107 in the inside surface 89 of container extension 27 and prevents the button 13 from being rotated around its attachment to the end of piston rod 69.

A nozzle 109 having a stem 111 fits through the wall of container extension 27 and communicates with the retainer passage 47. Surrounding the nozzle 109 is the mouthpiece 17 attached to the container 15. An opening 113 in the wall of container extension 27 communicates with the interior of the mouthpiece 17 and the space 115 below the actuator flange 87. On the opposite side of the container extension 27 is at least one vent opening 19 that communicates with a space 117 above the actuator flange 87.

Operation

Fig. 4 shows the valve in the uncocked position. Each detent ball 45 is confined in hole 43 between an edge 57 of stem guide 53 and edge 99 of actuator guide 91. The metering chamber 77 has been discharged and, in the position of Fig. 4, is filled with residual medicament or air, depending upon the time that has elapsed since the apparatus 11 was last operated.

The valve is cocked by pressing on button 13. The first change in position (shown in Fig. 5) moves the piston 67 into the metering chamber 77 stretching the piston seal 73 and eliminating any aerosol or air that is present in the metering chamber 77 by forcing it out through the orifice 79 and eventually through the nozzle 109 by means of the orifice chamber 49 and passage 47. This feature ensures that later when the metering chamber 77 is filled, it is completely filled with a completely fresh charge of medicament obtained from the container supply so that the dosage is a standard amount. Other constructions are possible for exhausting the material in the metering chamber 77 such as, for example, a plunger having O-rings around its outer surface to seal against the inside surface of the metering chamber 77. The construction shown in the drawings is preferred because of its positive seal.

As the operator continues to apply force to button 13, piston 67 "bottoms" in metering chamber 77 and moves valve stem 51 upward against the force of spring 81 and the force of the propellant pressure in the container 15. The orifice 79 moves past seal 31 and into the container 15. The valve stem 51 moves upward until the inclined edges 59—59 pass the detent balls 45—45 (shown in Fig. 6). The detent balls 45—45 are thus free to move toward the valve stem 51.

The button 13 is pushed still farther upward to the position shown in Fig. 7. At about the position of Fig. 6 the rim 119 of button 13 contacts a washer 121 positioned against actuator flange 87. The washer 121 has tabs 123—123 bent to provide a spring force between button 13 and actuator 85 while the button rim 119 and actuator flange 87 are in close proximity. After the button rim 119 contacts the washer 121 the actuator 85 is forced upward until the actuator flange 87 contacts the retainer flange 33. As the actuator moves upward, the inclined edge 99 of projection 95 moves the detent balls 45—45 inwardly toward valve stem 51. When button 13 is pushed upward as far as it will go, each detent ball 45 is loosely confined by the sides of the hole 43, valve stem guide edge 59 and actuator projection edge 97.

Fig. 8 shows the apparatus after the button 13 is released. The pressure in the aerosol container 15 forces piston 67 from the metering chamber 77 filling the chamber 77 with medicament. The valve stem 51 also tends to be forced downward by the pressure in the container 15, aided by the force of spring 81, until the inclined edges 59—59 of guides 53—53 contact the detent balls 45—45. The detent balls 45—45 are held against the edges 59—59 by the edges 97—97 of the actuator projections 95—95 preventing the valve stem from moving further downward. The actuator 85 tends to follow the button 13 when it is released but is initially prevented by the spring force produced by the tabs 123—123 on washer 121. The actuator 85 is therefore held against the retainer flange 33 until the guide edges 59—59 exert pressure on detent balls 45—45. When the detent balls 45—45 are forced outward by the guide edges 59—59 pressure is exerted on the parallel edges 97—97 of actuator projections 95—95 and prevents the actuator 85 from moving after the button 13 is released completely. At this point, the metering chamber 77 is filled and positioned in the container 15. If the actuator 85 is moved downward the detent balls 45—45 are released and the valve stem 51 can also move downward until the enlarged plug end 75 comes to rest against gasket 31. Note that in the position of Fig. 8, the button opening 103 coincides with the container extension opening 113.

With the valve cocked (as shown in Fig. 8), the patient places the mouthpiece 17 in his mouth (as shown in Fig. 2) and inhales or sucks on the mouthpiece. This causes a partial vacuum in the space 115 below actuator rim 87. The atmospheric pressure in the space 117 above the actuator flange 87 forces the actuator 85 downward as shown in Fig. 9. Movement of the actuator 85 downward causes the edges 97—97 of the actuator projections 95—95 to pass the detent balls 45—45. The detent balls 45—45 are thus free to move outwardly and release the valve stem 51.

After the valve stem 51 is released, it moves rapidly to the position of Fig. 10. In the meantime, the patient is still inhaling. The orifice 79 moves opposite the orifice chamber 49 and releases the medicament from the metering chambers 77 to the nozzle 109. The patient at this time draws the medicament deep into his respiratory tract. When button 13 moves downward with the valve stem 15 during inhalation, the opening 103 passes by the end of container extension 27. This allows the patient to obtain air for continued inhalation by opening space 115 to the atmosphere so the patient has a source of air for continued inhalation carrying the medicament into his lungs. Otherwise, the patient's inhalation would be curtailed as soon as the pressure in space 115 was reduced to a value that caused the patient to "struggle" to get air. The air that is admitted through

opening 103 into space 115 also supplies air for vaporization of the medicament.

Figs. 11 and 12 show a construction for another embodiment of a dosage apparatus 11'. Features of the constructions shown in Figs. 11 and 12 are also usable for the dosage apparatus 11 shown in Figs. 1—10. The dosage apparatus 11' has essentially the same external appearance as that shown in Fig. 1.

The valve stem 51' is constructed with an enlarged portion 125 that completely encircles the stem 51'. The enlarged portion 125 has an inclined surface 127 at the lower end and inclined surface 128 at the upper end. The enlarged portion 125 replaces the guides 53 shown in Figs. 1—10.

The retainer 29' is provided with a plurality of fingers 129—129 each having an enlarged end 131. The enlarged end 131 of each finger 129 is provided with an inclined surface 133 positioned to engage the inclined surface 127 of the valve stem 51'. The fingers 129—129 replace the holes 43—43, and detent balls 45—45 shown in Figs. 1—10.

The actuator 85' has an inwardly projecting annular ridges 135 with an inclined surface 137. The annular ridge 135 replaces the projections 95 shown in Figs. 1—10.

The apparatus 11' is shown in the locked position. The spring 81 is omitted in this embodiment since the force of the propellant is sufficient to move the valve stem 51' downward. The fingers 129 are bendable, and when the patient inhales, thereby moving the actuator 85' downward, the fingers 129 which were held against enlarged portion 125 are released so that they are free to move outward away from stem 51' disengaging the enlarged portion 125 so that the stem can move downward.

To cock the apparatus 11' the button 13' is pushed upward forcing the enlarged portion 125 past the enlarged finger ends 131—131. The inclined surface 128 forces the ends 129—129 apart. After the inclined surface 127 is above the inclined surfaces 133 of each finger 129—129, the inclined surface 137 of annular ridge 135 forces the fingers 129 inwardly and holds them in engagement with enlarged portion 125. This holds the valve stem 51' in the upward position until the actuator 85' moves downward and frees the finger ends 131 so that they can be forced outward by the inclined surface 127 and thereby release the valve stems 51'.

Most devices that dispense aerosol materials are disposed of after the container is empty. The embodiment shown in Fig. 11 is constructed so that the supply of medicament may be replaced. The container 15' is constructed with a first chamber 139 and a second chamber 141. The chambers are divided by a partition 143 having an opening 145 with the opening 145 surrounded by a gasket 147. A puncturing device 149 has a point 151 projecting into the opening 145. The top of the container is provided with threads 153. A bottle 155 having a thin seal 157 over the bottle opening 158 is also provided with threads 159 at its other end. The bottle neck 161 is inserted into the partition opening 145 and then threaded into position in the container 15. Suitable lugs 163 are provided so that the bottle 155 can be twisted to engage the threads 153 and 159. As the bottle 155 is threaded into container the puncturing device 149 breaks the seal 157 so that the contents of the bottle 155 are released to the first chamber 139. The gasket 147 keeps the first chamber 139 sealed off from the second chamber by being squeezed against the bottle neck 161.

Fig. 13 shows a construction for a manually released aerosol device 211. The device uses the features that are responsible for releasing a standard quantity of aerosol, but omits the features that are responsible for pneumatically releasing the device after it has been cocked. The valve portion 221 is mounted on a container 215. The container 215 has a flange 223 around an opening 225 and an extension 227 projecting below the flange 223 that aids in enclosing and retaining the valve portion 221.

A valve body 229 is fitted into the container extension 227 over the opening 225 and fits against a seal such as a gasket 231. The valve body 229 is cylindrical with a flange 233 at one end. A central bore 235 passes through the valve body 229 and has a larger diameter, centrally located relief portion 237. At the location of flange 233, the valve body 229 is provided with an orifice chamber 249 in the surface of bore 235. A passage 247 communicates between the exterior of flange 233 and orifice chamber 247.

A metering plunger 250 having a valve stem 251 is fitted snugly into bore 235 and extends from both ends of bore 235. The valve stem 251 has two centrally located bores. One is a piston bore 263 that communicates with one end of the valve stem 251 and the other is a smaller piston rod bore 265 that extends from piston bore 263 to the opposite end of valve stem 251. An expurgatory piston 267 fits into bore 263. A piston rod 269 attached to piston 267 fits into bore 265 and extends from one end of the valve stem 251. The metering plunger 250 also includes a plug 271 that is press-fitted to valve stem 251 over the end opening of bore 263. An expurgatory piston seal 273 is disposed between the end of stem 251 and plug 271 covering the end of piston 267. The cylindrical sidewall 274 of plug 271 engages the inner edge of gasket 231 in a sliding sealing fit. A gasket 276 is provided in bore 235 below orifice chamber 249 to create a seal between valve stem 251 and bore 235. The

plug 271 has an enlarged end 275 that bears on seal 231 preventing the stem 251 from moving out of bore 235. A metering chamber 277 is centrally located in plug 271 and has an orifice 279 communicating with the outside surface of plug 271 that, in the position of the apparatus as shown in Fig. 13, communicates with orifice chamber 249. A button 280 is affixed to the end of piston rod 269 providing a surface to press on when the apparatus 211 is to be cocked.

A plate 282 is attached to valve body 229 and provides a mounting foundation for the manually operated detent appratus 284. The detent apparatus is preferably a pivotally mounted arm 286 having a hook 288 at one end and is attached to a spring 290 at the opposite end. An extension 292 is provided on the spring attached end of arm 286.

Mounted at the bottom of valve portion 221 is cap 298, which may be press-fitted or screw-fitted to the valve portion 221. This cap includes the detent release mechanism 320 having a release button 296 at the bottom of push rod 294 extending downwardly outside the cap 298. The push rod 294 is normally biased downwardly by spring 321 acting between collar 322 secured to push rod 294 and sleeve 323, which is a part of cap 298. Buttons 280 and 296 are threaded or press-fitted onto the rods 269 and 294, respectively, to facilitate assembly.

Pressing button 280 purges chamber 277 and moves the metering chamber 277 into the container 215 by moving the plunger 250 upward. When the end of plunger 250 passes hook 288, the spring 290 forces the hook 288 over the end 300 of valve stem 251 and holds the plunger upward. By pressing release button 296, push rod 294 bears on extension 292 forcing the hook 288 out of engagement with the end 300 of valve stem 251 allowing the pressure in container 215 to force the plunger 250 downward releasing the contents of metering chamber 277 to the nozzle 309.

The above-described apparatus, except for the spring 73 and seals, is preferably constructed from a plastic material which makes it light and inexpensive. Various parts can be glued into position. Other materials are, of course, also acceptable, but the construction of the apparatus, unlike conventional valves, is especially suited for plastic materials.

In summary, this invention as embodied in the construction of Figs. 1—10, includes a pocket-size container 11 containing a mixture of finely divided solid material (such as a medicament) and a propellant that is gaseous at room temperature, but most of which is liquid under the above atmospheric pressure at room temperature to which it is subjected in the container. The finely divided solid material is substantially insoluble in the liquid propellant. There are means 21 for dispensing, in aerosol form, a definite small amount of the solid material in the container 15 upon each actuation of the means 21. A gasket 31 closes off the container 15 near the container opening 25. The dispensing means 21 and container opening 25 are at the lowermost end of the dispensing apparatus 11 when the dispensing apparatus 11 is in the operating position. A generally cylindrical metering plunger 50 having an outer end portion, such as valve stem 51, is connected to an inner end portion, such as valve stem plug 71. The gasket 31 has an opening therein that fits around the exterior surface 74 of the valve stem plug 71 on the metering plunger 50 and provides a seal thereat while the metering plunger 50 is moved axially toward and away from the interior of the container 15 between a depressed position and an extended position of the metering plunger 50 relative to the container 15. The valve stem plug 71 on the metering plunger 50 has a small hollow metering chamber 77 therein and also a passageway between the metering chamber 77 and an opening 79 in the exterior sidewall 74 of the valve stem plug 71 of the metering plunger 50. The opening 79 is positioned axially on the valve stem plug 71 on the metering plunger 50 so that it is on the container 15 side of the gasket 31 when the metering plunger 50 is in the depressed position and so that the opening 79 is on the exterior side of the gasket 31 when the metering plunger 50 is in the extended position. The opening 79 connects with the portion of the metering chamber 77 which is lowermost when the apparatus 11 is in the discharging position so that most of the contents of the metering chamber 77 drain downwardly out through the opening 79 when the metering plunger 50 is in the extended position. This results in a rapid and complete discharge of the metering chamber 77. The metering plunger 50 includes a movable member, such as piston 67 for moving a wall of metering chamber 77, such as piston seal 73. The movement of the wall or seal 73 is from a chamber-forming position, in which the metering chamber 77 has its normal volume, to a chamber-collapsed position, in which the metering chamber has substantially no volume. Operating means are available, such as button 13, for moving the metering plunger 50 against the action of a spring 81 into the depressed position so that the metering chamber 77 is filled through the opening 79 with an accurately determined small amount of the contents of the aerosol container 15. The button 13 also moves the movable member 67 from chamber-forming position to chamber-collapsed position before the button 13 moves the metering plunger 50 to the depressed position, thereby expelling the air from the metering chamber 77

before the metering chamber opening 79 passes from the exterior side to the container side of the gasket 31. A latch, including the detent balls 45—45, valve stem guide 53—53 and actuator projection 95, secures the metering plunger 50 in depressed position and thereafter releases the metering plunger 50 so that the metering plunger 50 becomes responsive to the spring 81 and moves to the extended position. The release of the operating means button 13, after the metering plunger 50 is moved to the depressed position, causes the movable member 67 to move from a chamber-collapsed to a chamber-forming position before the metering plunger 50 is released from the depressed position. This enables the metering chamber 77 to be filled with the desired measured amount of the contents of the container 15, before the metering plunger 50 moves to the extended position and discharge the contents of the metering chamber 77 into the mouthpiece 17.

The latch for securing the metering plunger 50 in depressed position could, if desired, be arranged to be released manually, as shown in Fig. 13. In the embodiments shown in Figs. 1—10, the latch is released automatically in response to inhalation by the user. This pneumatic release is achieved by providing a movable member 87 (i.e., the flanged end 87 of actuator 85) with an air chamber 117 on the upper side thereof and another air chamber 115 on the bottom side thereof, and by providing an opening 19 from the upper air chamber 117 to the atmosphere, and an opening from the lower air chamber 115 to the mouthpiece 17. Hence, inhalation by the user creates a reduced pressure on the under side of movable member 87, so it moves downwardly (see Fig. 9) and thereby releases the latch.

As a concrete illustration of some of the advantages of the aerosol device of this invention, whether manually released or pneumatically released, a device constructed as described in Figs. 1—10 discharges an unusually small metered dose of material—about 35 milligrams by weight (or about 25 microliters by volume as measured in the containers), where the active medicament in the aerosol container is a finely divided solid that is substantially insoluble in the propellant, with the amount of active medicament, in each dose discharged by the device, uniform to a remarkable degree over many successive doses until the container is substantially empty, regardless of the length of time transpiring between doses, and without introducing air into the container as the device is used, and so without introducing into the container something that might cause chemical instability in the medicament. The metering chamber 77 could, if desired, be made still smaller than 25 microliters without changing the principles of operation of the aerosol device.

While the invention is particularly useful with finely divided solid medicaments that are substantially insoluble in the "freon" types of propellants that are commonly used at the present time in aerosol devices, and particularly where it is desired to have such a medicament delivered deep into the respiratory system of a person, various aspects of the invention are also useful where the medicaments (whether solid or liquid) are soluble in the propellants, and where the material propelled by the propellants is not a medicament.

WHAT WE CLAIM IS:—

1. An aerosol container and spray device for use in administering small measured amounts of the contents of the aerosol container to a human being through his mouth or nostril, said device including:

(a) container for a pressurized fluid and a metering chamber for measuring small amounts of the pressurized fluid;

(b) manually actuated means for filling said metering chamber with said small amount of pressurized fluid from the remainder of the pressurized fluid in the container; and

(c) conduit means for directing the metered amount of pressurized fluid in the form of the human being, when the said of a spray into the mouth or nostril amount of pressurized fluid is released from the metering chamber, in which:

(i) the said manually actuated means may be released without enabling any fluid which may be contained in the metering chamber from escaping into the conduit means; and

(ii) the device includes means for releasing the contents of the metering chamber into the conduit means whereby the fluid can pass into the respiratory tract of the individual.

2. An aerosol container and spray device according to claim 1, in which the means for releasing the contents of the metering chamber into the conduit means is breath actuated.

3. An aerosol container and spray device according to Claim 2, in which the breath actuated means is responsive immediately to a significant reduction of air pressure in the conduit means from normal air pressure, thereby releasing the contents of the metering chamber into said conduit means at the beginning of the individual's inhalation.

4. An aerosol container and spray device according to either claim 2 or claim 3, in which the breath actuating means includes means for admitting air relatively freely to the conduit means, for inhalation by the

individual, as soon as the contents of the metering chamber are released into the conduit means.

5. An aerosol container and spray device according to claim 1, in which the means for releasing the contents of the metering chamber into the conduit means is manually operated.

6. An aerosol container and spray device according to any preceding claim, in which the container has an open end, a generally cylindrical metering plunger which is movable axially toward and away from the interior of the container between a depressed position and an extended position relative to said container; and a gasket near the open end of the container, said gasket having an opening which fits around the exterior sidewall of the plunger and provides a seal, wherein the metering chamber is located in said plunger and the means for introducing a small amount of pressurized fluid into the metering chamber comprises an orifice communicating between the metering chamber and the sidewall of the plunger, said orifice being positioned axially on the plunger so that it is on the container side of the gasket when the plunger is in the depressed position and on the exterior side of the gasket when the plunger is in the extended position; and wherein the container is provided with operating means, for controlling and operating the metering plunger, which comprises:

(i) a manually operated device connected to the plunger for moving the plunger, against the action of the propellant pressure, from the extended position to the depressed position in which position, the metering chamber is filled through the orifice with a pre-determined amount of the contents of said container;

(ii) detent means for securing the metering plunger in the depressed position; and

(iii) a breathing tube for connecting the aerosol device to said breathing opening of the human being by which the human being can inhale through the breathing tube, the metering chamber orifice being positioned to discharge the contents of the metering chamber into the breathing tube near the end which is placed in the mouth or nostril of the human being when said metering plunger is in the extended position.

7. An aerosol container and spray device according to claim 6, provided with a release means, independently operable after the manually-operated device has moved the metering plunger to the depressed position, for releasing the detent means thereby enabling the metering plunger to move from the depressed position to the extended position to effect the discharge of the contents of the metering chamber through the orifice.

8. An aerosol container and spray device according to claim 7, in which the release means is provided with a control which can be manually pushed inwards into the device to actuate the said release means to release the detent means.

9. An aerosol container and spray device according to claim 7, in which the release means is breath-actuated in that the reduced air pressure in the breathing tube caused by an attempt to breath in through said breathing tube actuates the means for releasing the detent means, thereby enabling the propellent pressure to move the plunger from the depressed position to the extended position and enable the contents of the metering chamber to be discharged into the mouth or nostril of the human being.

10. An aerosol container and spray device according to any one of claims 6 to 9, in which the metering plunger includes a movable member serving as a wall for the metering chamber, the movement of said member being from a chamber-forming position in which the metering chamber has a pre-determined volume, to a chamber-collapsed position in which the metering chamber has substantially no volume, the device including a mechanism for moving the movable member from the chamber-forming position to the chamber-collapsed position before the manually-operated device moves the metering plunger to the depressed position, thereby expelling air from the metering chamber before the metering chamber orifice passes from the exterior side to the container side of the gasket, the manually-operated device being effective, after the metering plunger is moved to the depressed position, to cause the movable member to move from the chamber-collapsed position to the chamber-forming position before the metering plunger moves sufficiently towards the extended position to move the metering chamber orifice from the chamber side of the gasket, thereby enabling the metering chamber to be completely filled with the desired measured amount of the contents of the container, before the metering plunger moves to its extended position and discharges the contents of said metering chamber into said breathing tube.

11. An aerosol container and spray device according to any one of claims 6 to 9, which includes a piston movable in the chamber to reduce the volume of said chamber from its normal metering capacity to a volume which is a small fraction thereof; and actuating means effective to move the piston to its small volume position just before the plunger is moved from the extended position to the depressed position, so that most of the air is removed from the chamber before said chamber is in communication with the interior of the container.

12. An aerosol container and spray device according to Claim 11, in which the piston actuating means is also effective, when the plunger reaches its depressed position, to move the piston from its small volume position to its original normal metering position, thereby causing the chamber to fill to its normal capacity with the pressurized fluid in the container.

13. An aerosol container and spray device according to any one of claims 6 to 12, in which a resilient means is positioned to urge the plunger from its depressed position toward its extended position.

14. An aerosol container and spray device according to claim 13, in which the resilient means comprises a coil spring.

15. An aerosol container or spray device according to any one of claims 6 to 14 which is provided with, in addition:

(i) actuator means, movable with the metering plunger from its extended position to its depressed position, said actuator means being positioned to engage and move the detent means into engagement with the metering plunger:

(ii) a valve comprising a valve body having a central bore and a communicating passage from said central bore to the mouthpiece;

(iii) an enclosure around the valve; and

(iv) a flange on the actuator means dividing said enclosure into a first space communicating with the mouth piece and a second space communicating with the atmosphere whereby a reduction of presure in the first space causes the actuator means to release the detent means from engagement with the metering plunger and allowing said metering plunger to move from its depressed position to its extended position.

16. An aerosol container and spray device according to claim 6, including a mechanism which, upon initial operation of the manually-operated device, removes substantially all of the air from the metering chamber before the metering plunger moves sufficiently to move the orifice from the exterior side of the gasket, and thereupon prevents the inflow of air into the metering chamber while the metering plunger is moved to the depressed position, the mechanism, after said metering plunger is moved to the depressed position, operating to admit to the metering chamber sufficient of the contents of the aerosol container to fill the metering chamber, before the restoring force acts to move the metering plunger into the extended position.

17. An aerosol container and spray device according to claim 16, in which the metering plunger includes a movable member serving as a wall for the metering chamber, the movement of said member being from a chamber-forming position in which the metering chamber has its normal volume, to a chamber-collapsed position in which the metering chamber has substantially no volume, and in which the mechanism of the manually-operated device moves the movable member from the chamber-forming position to the chamber-collapsed position before the metering plunger moves from the extended to the depressed position, thereby expelling the air from the metering chamber before the metering chamber orifice passes from the exterior side to the container side of the gasket.

18. An aerosol container and spray device according to claim 17, in which the operating means is effective, after the metering plunger is moved to the depressed position, to cause the movable member to move from the chamber-collapsed position to the chamber-forming position before the metering plunger moves sufficiently toward the extended position to move the metering chamber orifice from the chamber side of the gasket, thereby enabling said metering chamber to be completely filled with the desired measured amount of the contents of the container, before the metering plunger moves to its extended position and discharges the contents of the metering chamber.

19. An aerosol container and spray device according to claim 18, including a release means, independently operable after the manually-operated device has moved the metering plunger to the depressed position, for releasing the detent means and thereby enabling the metering plunger to move from the depressed position to the extended position to effect the discharge of the contents of the metering chamber through said orifice.

20. An aerosol container and spray device substantially as hereinbefore described with reference to Figs. 1 to 10, Figs. 11 and 12, or Figs. 13 and 14 of the accompanying drawings.

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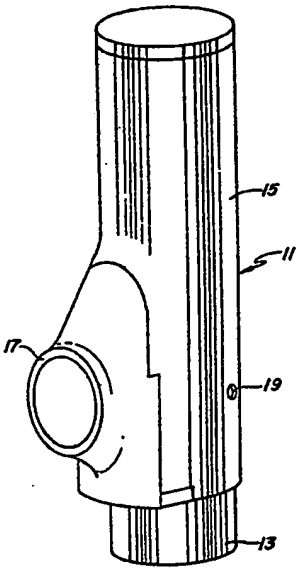

FIG. 1

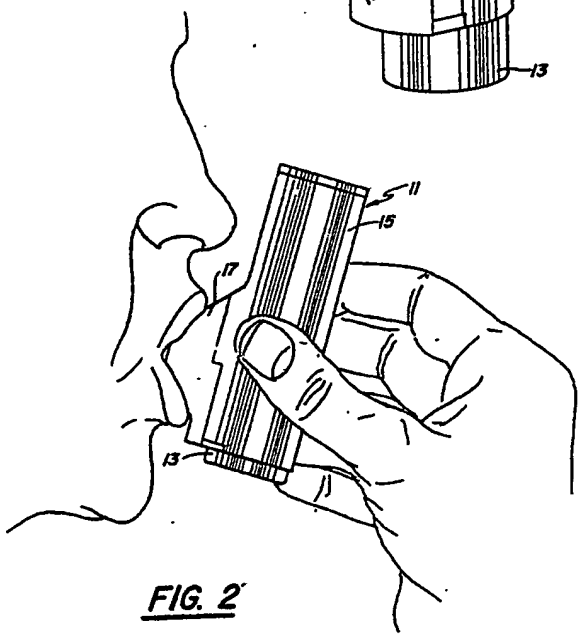

FIG. 2

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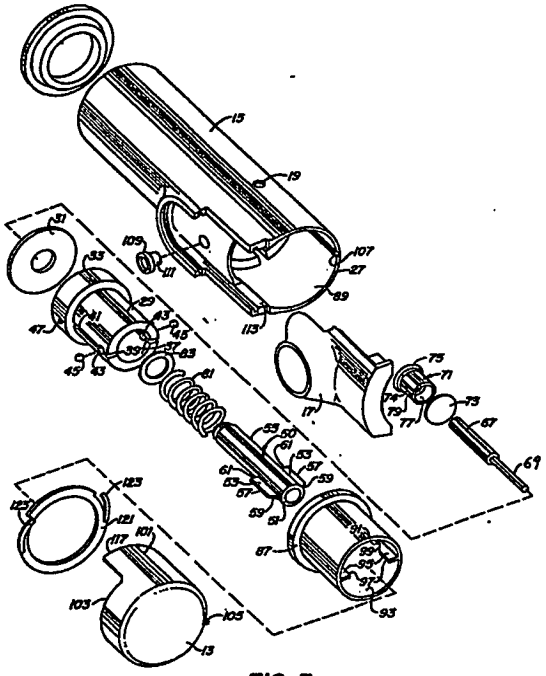


FIG. 3

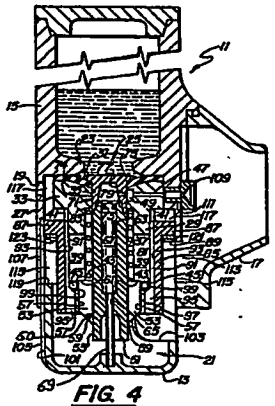


FIG. 4

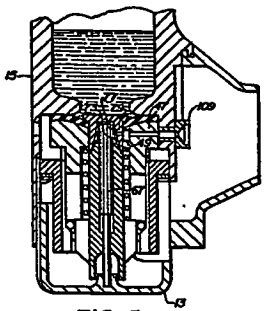
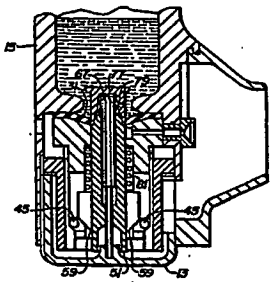


FIG. 5



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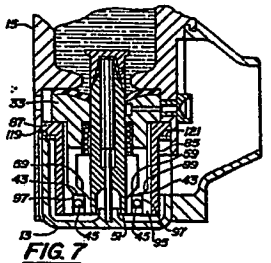

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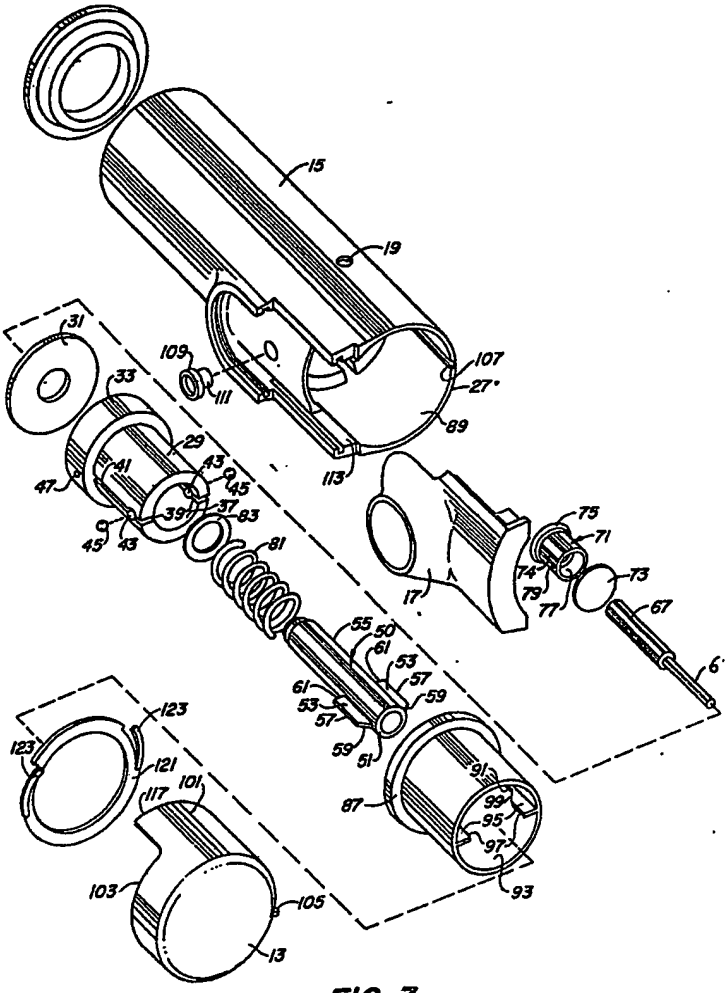
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FIG. 3

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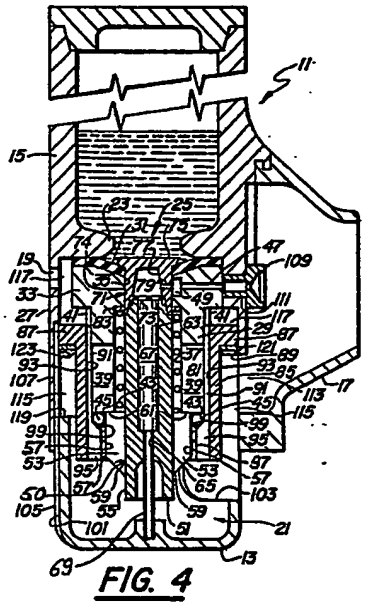

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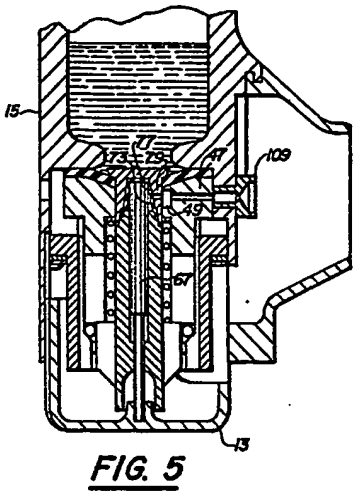

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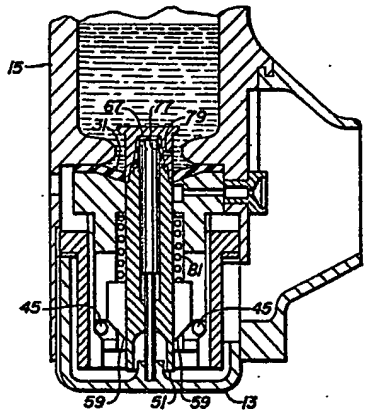

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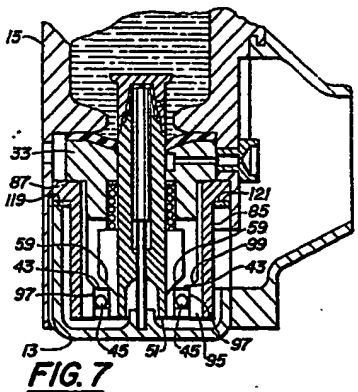

FIG. 7

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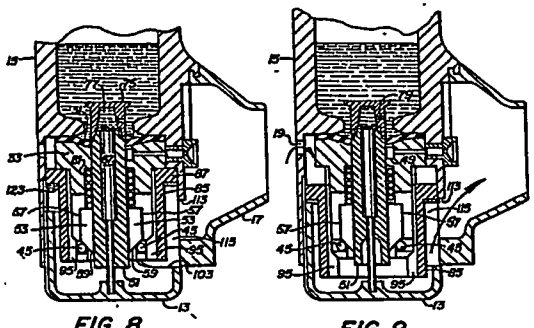


FIG. 8

FIG. 9

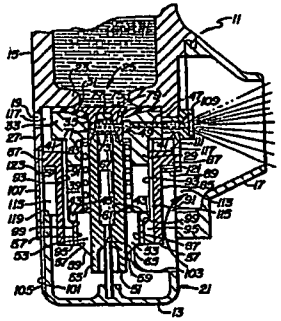


FIG. 10

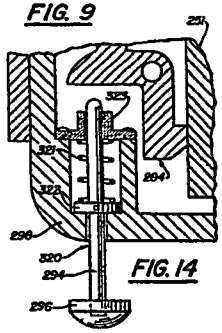


FIG. 14

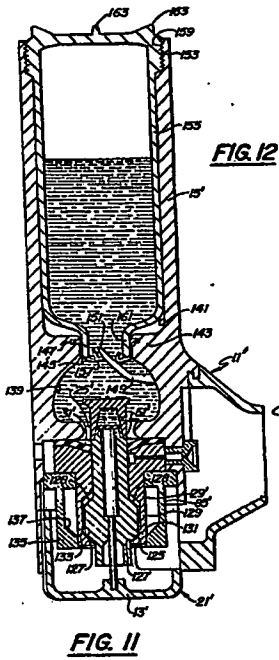


FIG. 11

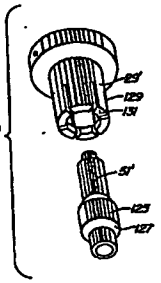


FIG. 12

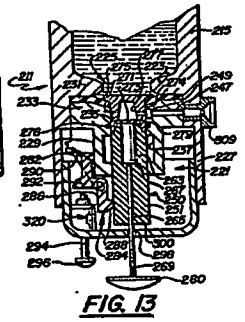
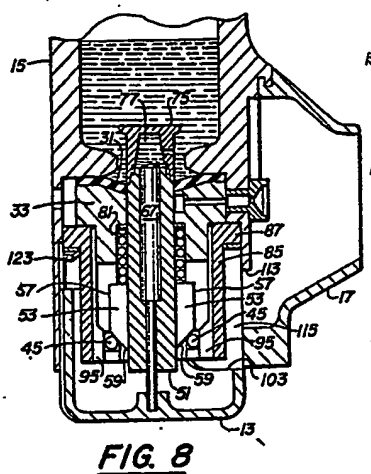


FIG. 13



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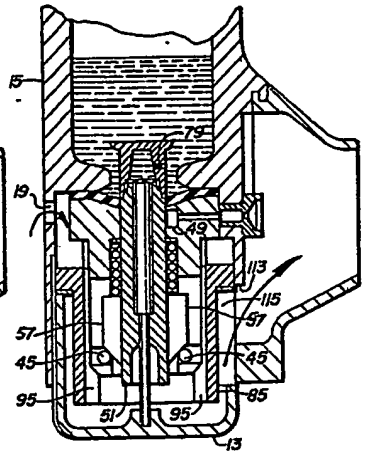

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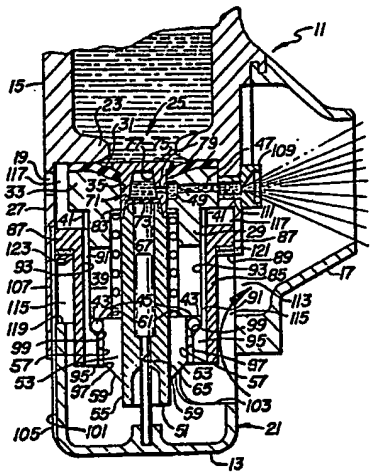

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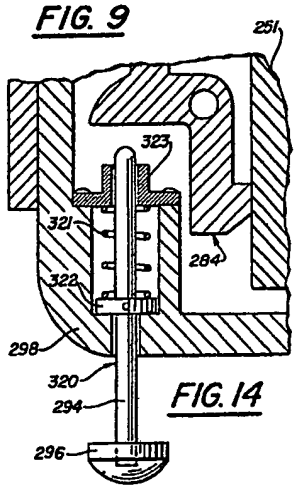

FIG. 14

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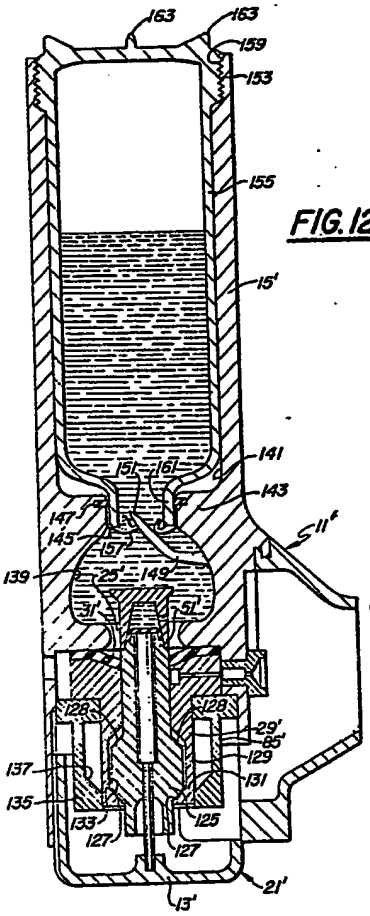

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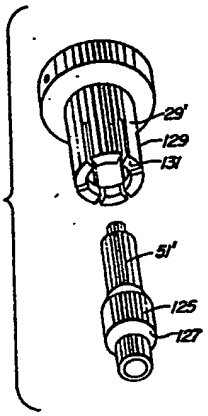

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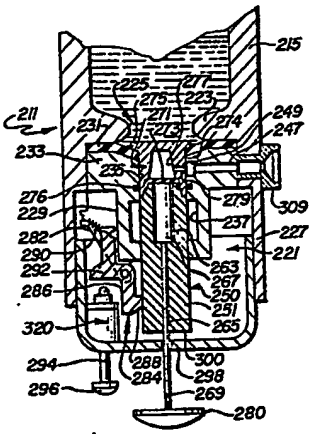

FIG. 13

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